

**Notice of Allowability**

Application No.

10/083,776

Applicant(s)

Examiner

Blessing M. Fubara

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 02/08/04.
2. ☒ The allowed claim(s) is/are 85-92 (claims are renumbered).
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
  1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |   |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                                 |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date <u>0/11/04</u> . |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date <u>02/02/04</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment   |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material                               | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance                        |
|  | 9. <input type="checkbox"/> Other _____.  |

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### **DETAILED ACTION**

Examiner acknowledges receipt of IDS, request for extension of time, amendment and remarks filed 02/08/04. Claims 85-92 are pending.

#### ***Oath/Declaration***

Applicants submitted declaration on July 30, 2002 in response to file missing parts. However, the complete declaration is not in the electronic file. Applicants agreed to FAX the complete set to Examiner.

### **EXAMINER'S AMENDMENT**

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Joseph S. Kentoffio on 06/11/04.

The application has been amended as follows:

In claim 92, line 2, replace "levaquin" with ---levofloxacin---

#### ***Allowable Subject Matter***

2. The following is an examiner's statement of reasons for allowance: Applicants claim a solution that comprises a quinolone carboxylic acid antibiotic and a taste masking composition

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that comprises from about 0.05 to about 2.5 gram sucralose per 100 mL of the solution, up to about 120 gram sugar sweetener per 100 mL of the solution and at least one flavoring agent.

The closest prior art of record are Yu et al. (US 6,482,823) and Lee (US 6,391,886). Yu discloses a liquid composition that comprises quinolone antibiotic (levofloxacin or ofloxacin), flavoring agents and sucrose sweetener in an amount of 2.5 g/5 mL, which is 50g/100 mL (abstract; column 2, lines 15-34; column 3, lines 7-19 and 29-40; column 4, lines 25-36; Table 4 and claim 11). Yu does not show or suggest the inclusion of sucralose in the composition. Lee discloses a liquid composition that comprises antibiotics, from about 0.4% to about 3.3% (i.e. 0.004 to 0.033g/100 mL) sucralose and a second sweetener (column 4, lines 6-8 and lines 30-60). Lee discloses that artificial sweetener such as sucralose used in high levels result in compositions that have bitter, metallic or other objectionable taste (column 2, lines 50-52) and thus used about 0.004 to 0.033g/100 mL and these amounts are outside the range of amounts required in the instant claim. Lee discloses antibiotics broadly and fails to disclose any antibiotics let alone quinolone antibiotics. The second sweeteners disclosed did not include sucrose. The prior art does not show specific taste masking amounts of sweeteners in combination with quinolone antibiotic in a liquid or solution. Therefore, the pending claims are allowable.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 242-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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